UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

October 23, 2012

MEMORANDUM

Subject: Efficacy Review for GNR; EPA File. No. 67619-GN; DP Barcode: D404017.

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Applicant: Clorox Professional Products Company
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P.O. Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredient	% by wt.
Sodium hypochlorite	0.39 %
Other Ingredients	99.61 %
Total	100.00 %

I. BACKGROUND

The product, GNR (EPA File Symbol 67619-GN), is a new registration. The applicant requested to obtain a registration for use as a hospital disinfectant (bactericide, fungicide, virucide) and deodorizer for hard, non-porous surfaces for household, hospital, and institutional environments. Studies were conducted at ATS Labs (1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121).

GNR is a spray product which consists of 2 separate chambers, a bleach (sodium hypochlorite) chamber and a neutralizer chamber. The two chambers will be fully enclosed and a label will encompass both chambers. When the product is sprayed from the trigger, the result is a mixture consisting of equal portions of the bleach and neutralizer chambers. Note: this "neutralizer" chamber does not inactive or neutralize the active ingredient. The hypochlorite and neutralizer solutions were assigned individual batch codes (i.e. 11gnr01 and 11gnr02), which were combined upon testing (i.e. 11gnr01/02). All batches of product were analyzed to verify the active ingredient level was at or below the Lower Certified Limit (LCL) for efficacy testing.

Three batches, with one aged ≥60 days were tested against *Pseudomonas aeruginosa, Salmonella enterica,* and *Staphylococcus aereus* to support the hospital disinfectant claim. After testing was complete, it was determined the neutralizer batch 11gnr02 had one inert ingredient outside of the certified limits. Thus a new neutralizer solution, batch 11gnr17, was provided and testing repeated using three new protocols (A12627, A12628, A12629). This new mixture also obtained passing results for all tests. Al the final reports were submitted for each set of testing.

This data package contained letters from the applicant to EPA (dated July 12, 2012), 34 new studies (MRID Nos. 488850-11 through 488850-45), Statements of No Data Confidentiality Claims for all 34 studies, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: appliance exteriors, cabinets, carts, counters, doorknobs, garbage cans, shower fixtures, sinks, and walls. The proposed label indicates the product may be used on hard, non-porous surfaces, including baked enamel, chrome, Formica, glass, glazed tile, laminated surfaces, Marlite®, Naugahyde, plastic, Plexiglas®, sealed fiberglass, stainless steel, synthetic marble, vinyl and similar hard, [finished and/or painted] nonporous surfaces. Directions on the proposed label provide the following information regarding use of the product:

> **As a Disinfectant**: To [Clean and] Disinfect [and Deodorize] Hard, Nonporous Surfaces: Spray 6-8 inches from surface until surface is thoroughly wet. Allow this product to remain wet for 1 minute. Then wipe. For heavily soiled areas, a precleaning is required. Rinse with potable water for food-contact surfaces. For all others, no rinsing is required.
> **For Killing Clostridium difficile spores:** Clean hard, nonporous surfaces by removing gross filth. Spray 6-8 inches from surface until surface is thoroughly wet. Allow product to remain wet for 1 minute for Clostridium difficile. Then wipe.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sporicidal Disinfectant against *Clostridium difficile:* The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a

product must be substantiated by data derived from one of the following four test methods: Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes*; AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes* and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 488850-12 "AOAC Germicidal Spray Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – February 20, 2012. Project Number A12376.

The active ingredient concentration of Batch 11gnr01 was reported to be 0.351% sodium hypochlorite, Batch 11gnr03 to be 0.340% sodium hypochlorite, and Batch 11gnr05 to be 0.343% sodium hypochlorite.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Batch 11gnr01/02 (aged ≥60 days), 11gnr03/04, 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C at 43% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 40 seconds on test date at 21°C and 32% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Staphylococcus aureus* was 6.67 Log_{10}.

Note: The protocol amendments reported in the study were reviewed.

2. MRID 488850-13 "AOAC Germicidal Spray Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – April 5, 2012. Project Number A12627.

The active ingredient concentration of Batch 11gnr01 (≥60 days old) was measured to be 0.351% sodium hypochlorite.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One aged lot (Batch 11gnr01/11gnr17 (≥60 days old)) of GNR was tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C at 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 24% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Staphylococcus aureus* was 6.86 Log_{10}.

3. MRID 488850-14 "AOAC Germicidal Spray Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – January 30, 2012. Project Number A12204.

Though not included in the report, based on the lot codes found in the related efficacy reports, the active ingredient concentration of Batch 11gnr01 (≥60 days old), was 0.351% sodium hypochlorite, Batch 11gnr03 was 0.340% sodium hypochlorite, and Batch 11gnr05 was 0.343% sodium hypochlorite.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Batch 11gnr01/02 (≥60 days old), 11gnr03/04, 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 23% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Salmonella enterica* was 4.46 Log_{10}.

Note: The protocol amendments reported in the study were reviewed.

4. MRID 488850-15 "AOAC Germicidal Spray Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – April 5, 2012. Project Number A12628.

The active ingredient concentration of Batch 11gnr01 (≥60 days old) was measured to be 0.351% sodium hypochlorite.

This study was conducted against *Salmonella enterica* (ATCC 10708). One aged lot (Batch 11gnr01/11gnr17 (≥60 days old)) of GNR was tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 23% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Salmonella enterica* was 4.42 Log_{10}.

5. MRID 488850-16 "AOAC Germicidal Spray Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – February 20, 2012. Project Number A12375.

The active ingredient concentration of Batch 11gnr01 (≥60 days old) was reported to be 0.351 % sodium hypochlorite, Batch 11gnr03 was reported to be 0.340% sodium hypochlorite, Batch 11gnr05 (≥60 days old) was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Batch 11gnr01/02 (≥60 days old), 11gnr03/04, 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 40 seconds at 21°C and 31% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Pseudomonas aeruginosa* was 6.22 Log_{10}.

Note: The reported protocol amendments were reviewed.

6. MRID 488850-17 "AOAC Germicidal Spray Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – April 6, 2012. Project Number A12629.

The active ingredient concentration of Batch 11gnr01 (≥60 days old) was measured to be 0.351% sodium hypochlorite.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Batch 11gnr01/11gnr17 (≥60 days old)) of GNR was tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C at 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 35 seconds at 20°C and 23% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Pseudomonas aeruginosa* was 6.39 Log_{10}.

7. MRID 488850-18 "AOAC Germicidal Spray Method, Test Organism: *Escherichia coli* O157:H7 (ATCC 35150)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – March 13, 2012. Project Number A12464.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 22.0°C and 12.1% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Escherichia coli* O157:H7 was 5.86 log_{10}.

8. MRID 488850-19 "AOAC Germicidal Spray Method, Test Organism: *Enterobacter aerogenes* (ATCC 13048)" for GNR F2011.0070, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – February 21, 2012. Project Number A12459.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The

carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horintal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 15% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for *Enterobacter aerogenes* was 7.16 $\log_{10}$.

9. MRID 488850-20 "AOAC Germicidal Spray Method, Test Organism: *Enterobacter cloacae* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000654)" for GNR F2011.0070, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – June 25, 2012. Project Number A12460.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Enterobacter cloacae* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000654). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 21.9°C and 15.0% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population. The average carrier population control for the test microorganism was 6.08 $\log_{10}$.

Note: Antimicrobial Susceptibility Testing was conducted on representative culture of the microorganism using E Test and MIC methods, against several β-lactam antibiotics. *Enterobacter cloacae* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000654) was found resistant to all β-lactam antibiotics used. See "Attachment I" on page 17 of the laboratory report.

10. MRID ######-## "AOAC Germicidal Spray Method, Test Organism: *Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000527)" for GNR F2011.0070, by Becky Lien. Study conducted at ATS Labs. Study completion date – June 25, 2012. Project Number A12465.

Though not included in the report, based on the lot codes and reports found in the related efficacy reports, the active ingredient concentration of Batch 11gnr03 was 0.340% sodium hypochlorite, and Batch 11gnr05 was 0.343% sodium hypochlorite.

This study was conducted against *Klebsiella pneumonia* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000527). Two lots (Batch 11gnr03/04 and batch 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters

of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 22.6°C and 14.3% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48+/-2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population. The average carrier population control for the test microorganism was 6.53 $\log_{10}$.

Note: Antimicrobial Susceptibility Testing was conducted on a representative culture of *Klebsiella pneumonia* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000527), using E Test and MIC methods, against several β-lactam antibiotics, and found to be resistant to all of them. See "Attachment I" on page 17 of the laboratory report.

11. MRID 488850-22 "AOAC Germicidal Spray Method, Test Organism: *Proteus mirabilis* (ATCC 9240)" for GNR F2011.0070, by Joshua Luedke. Study conducted at ATS Labs. Study completion date – May 2, 2012. Project Number A12622.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Proteus mirabilis* (ATCC 9240). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 35 seconds at 20°C and 21% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for the test microorganism was 6.88 $\log_{10}$.

12. MRID 488850-23 "AOAC Germicidal Spray Method, Test Organism: *Serratia marcescens* (ATCC 14756)" for GNR F2011.0070, by Nicole Albert. Study conducted at ATS Labs. Study completion date – February 21, 2012. Project Number A12462.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Serratia marcescens* (ATCC 14756). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8

inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 15% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for the test microorganism was 6.74 $\log_{10}$.

13. MRID 488850-24 "AOAC Germicidal Spray Method, Test Organism: *Acinetobacter baumannii* (ATCC 19606)" for GNR F2011.0070, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – April 10, 2012. Project Number A12621.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 35 seconds at 21°C and 20% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for the test microorganism was 5.49 $\log_{10}$.

14. MRID 488850-25 "AOAC Germicidal Spray Method, Test Organism: Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575)" for GNR F2011.0070, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 21, 2012. Project Number A12623.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 35 seconds at 22.4°C and 16.8% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic

resistance confirmation, and carrier population. The average carrier population control for the test microorganism was 5.45 $\log_{10}$.

Note: Antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. A Vancomycin disk was placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to Vancomycin. See page 16 of the laboratory report.

15. MRID 488850-26 "AOAC Germicidal Spray Method, Test Organism: Multidrug Resistant *Enterococcus faecium* (ATCC 51559)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – March 13, 2012. Project Number A12442.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Multidrug Resistant *Enterococcus faecium* (ATCC 51559). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 2 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 27% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population. The average carrier population control for the test microorganism was 5.98 $\log_{10}$.

Note: Antimicrobial Susceptibility Testing was conducted on a representative culture of Multidrug Resistant *Enterococcus faecium* (ATCC 51559), using MIC method, against several antibiotics, and found to be resistant to Ampicillin, Penicillin, Vancomycin, Gentamicin, Tobramycin, and Amikacin. See "Attachment I" on page 16 of the laboratory report.

16. MRID 488850-27 "AOAC Germicidal Spray Method, Test Organism: Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)" for GNR F2011.0070, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – May 2, 2012. Project Number A12830.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass

slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 37 seconds at 23.69°C and 16.79% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population. The average carrier population control for the test microorganism was 6.48 $\log_{10}$.

Note: Antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. An Oxacillin disk was placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) to Oxacillin (Methicillin). See page 17 of the laboratory report.

17. MRID 488850-28 "AOAC Germicidal Spray Method, Test Organism: Multidrug Resistant *Streptococcus pneumoniae* (ATCC 700677)" for GNR F2011.0070, by Becky Lien. Study conducted at ATS Labs. Study completion date – May 23, 2012. Project Number A12444.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Multidrug Resistant *Streptococcus pneumoniae* (ATCC 700677). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 3 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 27% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Brain Heart Infusion Broth containing 0.07% Lecithin, 0.5% Tween 80, and 0.05% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population. The average carrier population control for the test microorganism was 4.85 $\log_{10}$.

Note: Antimicrobial Susceptibility Testing was conducted on a representative culture of Multidrug Resistant *Streptococcus pneumoniae* (ATCC 700677), using E Test method, against several antibiotics, and found to be resistant to Penicillin (oral), Penicillin (meningitit), Ceftriaxone (meningitit), and Clindamycin. See "Attachment I" on page 16 of the laboratory report.

18. MRID 488850-29 "AOAC Germicidal Spray Method, Test Organism: *Stenotrophomonas maltophilia* (ATCC 25596)" for GNR F2011.0070, by Becky Lien. Study conducted at ATS Labs. Study completion date – April 13, 2012. Project Number A12466.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Stenotrophomonas maltophilia* (ATCC 25596). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 15% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth with 0.1% Sodium Thiosulfate. All subcultures were incubated for 2 days at 25-30°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for the test microorganism was 7.01 $\log_{10}$.

19. MRID 488850-30 "AOAC Germicidal Spray Method, Test Organism: *Campylobacter jejuni* (ATCC 29428)" for GNR F2011.0070, by Becky Lien. Study conducted at ATS Labs. Study completion date – February 24, 2012. Project Number A12488.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Campylobacter jejuni* (ATCC 29428). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 2 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C and 21% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL Letheen Broth containing 0.1% Sodium Thiosulfate. The contents were filtered using 0.45 micron filter. Each membrane was washed with ≥50 mL of sterile saline, and then placed on a surface of Tryptic Soy Agar with 5% Sheep Blood. All subcultures were incubated for 3 days at 35-37°C under microaerophilic conditions. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for the test microorganism was 4.23 $\log_{10}$.

20. MRID No. 488850-31, "Standard Quantitative Disk Carrier Test Method-Modified for Spray Applications," Test Organism: *Clostridium difficile* – spore form (ATCC 43598)," for GNR F2011.0070, by Nicole Albert. Study conducted at ATS Labs. Study completion date –June 15, 2012. Project Number A13107.

The active ingredient concentration of Batch 11gnr01 was reported to be 0.351% sodium hypochlorite, Batch 11gnr03 to be 0.340% sodium hypochlorite, and Batch 11gnr05 to be 0.343% sodium hypochlorite.

The study was conducted against *Clostridium difficile* spores (ATCC 43598). Three lots (Batch 11gnr01/17 (≥60 days old), 11gnr03/04, and 11gnr05/06) of GNR were tested using ASTM E2197, Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides, as specified by the US EPA in Guidance for the Efficacy Evaluation of Products with Sporicidal Claims Against *Clostridium difficile* (February 2009). Sterilized stainless steel disks were inoculated with 0.01 ml spore suspension demonstrating 98% purity. The Petri plates containing the inoculated carriers were transferred to a desiccator, and dried first overnight without a vacuum, at ambient conditions, then under vacuum for ≥2 hours at ambient conditions. Post-drying, each carrier was transferred to a new Petri dish, lined with filter paper. Each carrier was then treated with 8 sprays of the product, at a distance of 6-8 inches. Each carrier was exposed to the solution for 50 seconds at 21°C and 38% relative humidity. Post-exposure, each carrier was transferred to a sterile vial containing 10 ml neutralizer (Letheen Broth with 0.1% sodium thiosulfate). To elute surviving spores on test/control carriers, the carriers were scraped with a sterile loop and vortex mixed for approximately 45-60 seconds. For the control carriers, three carriers were treated individually in a sterile vial by spraying 0.85% saline with 0.1% Tween 80. Serial 10-fold dilutions of the neutralizing solution from each carrier were prepared. Three dilutions were each vacuum-filtered. For test carriers, 1 mL was removed and serially diluted while the remaining 9 mL volume of each 10^0 dilution vial was vacuum-filtered using separate sterile analytical filter units. Each vial was rinsed three times with 10.0 ml 0.85% saline, and the rinsates were filtered. Test and control membrane filters were transferred to the surface of CCFA-HT agar. The plates were incubated anaerobically at 35-37°C for 48±4 hours. Controls included those for HCl resistance, purity, sterility, neutralization effectiveness confirmation, initial suspension population control, and spore purity control. The average carrier population control for the test microorganism was 3.16×10^6 CFU/carrier.

Note: The reported protocol amendments were reviewed.

21. MRID 488850-32 "Fungicidal Germicidal Spray Method, Test Organism: *Candida albicans* (ATCC 10231)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – January 30, 2012. Project Number A12477.

The active ingredient concentration of Batch 11gnr03 was 0.340% sodium hypochlorite, and Batch 11gnr05 was 0.343% sodium hypochlorite.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the Fungicidal Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the suspension to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 3 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 1 minute at 22.3°C and 16.2% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth containing 0.07% Lecithin, 0.5% Tween 80, and 0.05% Sodium Thiosulfate to neutralize. All subcultures were incubated for 2 days at 25-30°C. Following incubation, the subcultures were examined for the

presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population control for the test microorganism was 5.77 $\log_{10}$.

22. MRID 488850-33 "Fungicidal Germicidal Spray Method, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for GNR F2011.0070, by Christine Chan. Study conducted at ATS Labs. Study completion date – February 21, 2012. Project Number A12478.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested using the Fungicidal Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 2009. Fetal bovine serum was added to the conidial suspension to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 10 day old suspension of fungal spores. The carriers were dried for 38 minutes at 35-37°C at 41% relative humidity. Each carrier in a horizontal position was sprayed with the product for 4 sprays until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 1 minute at 21.4°C and 17.9% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth containing 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average carrier population controls for the test microorganisms was 5.66 $\log_{10}$.

Note: The reported protocol deviation was reviewed.

23. MRID 488850-34 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus" for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – April 16, 2012. Project Number A12536.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Duck Hepatitis B Virus (obtained from Hepadnavirus Testing, Inc.) as a Surrogate Virus for Human Hepatitis B Virus, using duckling hepatocytes (from VRI Laboratories) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.DHBV.1 (copy provided). The stock virus culture was 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20.0°C at 40% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 21.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in test medium of Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Duckling hepatocyte cells in multi-well culture dishes were inoculated in quadruplicate with 0.25 mL of each dilution. The cultures were incubated at 36-38°C in a humidified

atmosphere of 5-7% CO_2 for nine days. On the final day of incubation, the cultures were observed for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by Most Probable Number statistics using the template provided by Big Sky Statistical Analysts LLC (Bozeman, MT).

24. MRID 88850-35 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus – Confirmatory Assay" for GNR F2011.0070, by Shanen Conway. Study conducted at ATS Labs. Study completion date – April 11, 2012. Project Number A12472.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite.

This study was conducted against Duck Hepatitis B Virus (obtained from Hepadnavirus Testing, Inc.) as a Surrogate Virus for Human Hepatitis B Virus, using duckling hepatocytes (from VRI Laboratories) as the host system. One lot (Batch 11gnr03/04) of GNR was tested according to ATS Labs Protocol No. CX18103111.DHBV.2 (copy provided). The stock virus culture was 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 21.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in test medium of Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Duckling hepatocyte cells in multi-well culture dishes were inoculated in quadruplicate with 0.25 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 for nine days. On the final day of incubation, the cultures were observed for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by Most Probable Number statistics using the template provided by Big Sky Statistical Analysts LLC (Bozeman, MT).

25. MRID 488850-36 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Herpes simplex virus type 1, Strain F(1), (ATCC VR-733)." for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – January 27, 2012. Project Number A12409.

The active ingredient concentration of Batch 11gnr03 was 0.340% sodium hypochlorite, and Batch 11gnr05 was 0.343% sodium hypochlorite.

This study was conducted against Herpes simplex virus type 1, Strain F(1), (ATCC VR-733), using RK cells (Rabbit Kidney cells; obtained from Viromed Laboratories, Inc.) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.HSV1 (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot were tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 21.0°C.

Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

26. MRID 488850-37 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Immunodeficiency Virus type 1, Strain HTLV-III_B." for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – January 27, 2012. Project Number A12400.

The active ingredient concentration of Batch 11gnr03 was 0.340% sodium hypochlorite, and Batch 11gnr05 was 0.343% sodium hypochlorite.

This study was conducted against Human Immunodeficiency Virus type 1 (obtained from Advanced Biotechnologies Inc.), using MT-2 cells (human T-cells; obtained through AIDS Research and Reference Reagent Program, Div. of AIDS, NIAID, NIH) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.HIV (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 22.0°C at 14.6% relative humidity. One replicate per product lot were tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 22.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in RPMI-1640 with 15% (v/v) heat-inactivated fetal bovine serum, 2.0 mM L-glutamine, and 50 µg/mL gentamicin. MT-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 13 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The reported protocol deviation was reviewed.

27. MRID 48850-38 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus, Strain Hong Kong (ATCC VR-544)" for GNR F2011.0070, by Shanen Conway. Study conducted at ATS Labs. Study completion date – January 27, 2012. Project Number A12453.

The active ingredient concentration of Batch 11gnr03 was 0.340% sodium hypochlorite, and Batch 11gnr05 was 0.343% sodium hypochlorite.

This study was conducted against Influenza A Virus, Hong Kong Strain (ATCC VR-544), using RMK cells (Rhesus Monkey Kidney cells; obtained from Viromed Laboratories, Inc.) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.FLUA (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared

by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

28. MRID 488850-39 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rhinovirus type 37, Strain 151-1 (ATCC VR-1147)" for GNR F2011.0070, by Shanen Conway. Study conducted at ATS Labs. Study completion date – March 12, 2012. Project Number A12404.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Rhinovirus type 37, Strain 151-1 (ATCC VR-1147) using MRC-5 cells (human embryonic lung cells; ATCC CCL-171) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.R37 (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 15.5°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 10% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

29. MRID 488850-40 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rotavirus, Strain WA" for GNR F2011.0070, by Shanen Conway. Study conducted at ATS Labs. Study completion date – April 11, 2012. Project Number A12407.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Rotavirus, Strain WA (obtained from University of Ottawa) using MA-104 cells (Rhesus monkey kidney) cells; obtained from Diagnostic Hybrids) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.ROT (copy provided). The stock virus culture was

adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed for 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin, and 2.0 mM L-glutamine. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

30. MRID 488850-41 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus" for GNR F2011.0070, by Shanen Conway. Study conducted at ATS Labs. Study completion date – February 23, 2012. Project Number A12402.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Feline Calicivirus, strain F-9 (ATCC VR-782), the surrogate for human Norovirus, using CRFK cells (Crandel Reese feline kidney cells; ATCC CCL-94) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR was tested according to ATS Labs Protocol No. CX18103111.FCAL.1 (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, two separate dried virus films were sprayed with 3 sprays until thoroughly wet at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization.

31. MRID 488850-42 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus – Confirmatory Assay" for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – April 17, 2012. Project Number A12403.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite.

This study was conducted against Feline Calicivirus, strain F-9 (ATCC VR-782), the surrogate for human Norovirus, using CRFK cells (Crandel Reese feline kidney cells; ATCC

CCL-94) as the host system. One lot (Batch 11gnr03/04) of GNR was tested according to ATS Labs Protocol No. CX18103111.FCAL.2 (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed with 3 sprays until thoroughly wet at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Just prior to the end of the exposure time, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by Most Probable Number statistics using the template provided by Big Sky Statistical Analysts LLC (Bozeman, MT).

32. MRID 488850-43 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus, 229-E strain (ATCC VR-740)" for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – April 16, 2012. Project Number A12408.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Human Coronavirus, 229-E strain (ATCC VR-740), using WI-38 cells (human lung cells; ATCC CCL-75; obtained from American Type Culture Collection) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.COR (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed with 3 sprays until thoroughly wet at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 2% (v/v) heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. WI-38 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for eleven days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

33. MRID 488850-44 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Respiratory syncytial virus, Strain Long, (ATCC VR-26)" for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – February 21, 2012. Project Number A12401.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Respiratory Syncytial Virus (Strain Long; ATCC VR-26), using Hep-2 cells (human larynx carcinoma cells; obtained from Viromed Laboratories, Inc.) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.RSV (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed with 3 sprays until thoroughly wet at a distance of 6-8 inches and held covered for 30 seconds at 20.0°C. Just prior to the end of the exposure time, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Eagle's Minimal Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, 10mM HEPES, 10 µg/mL vancomycin, and 2 mM L-glutamine. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for ten days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

34. MRID 48850-45 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H5N1) strain VNH5N1-PR8/CDC-RG CDC# 2006719965" for GNR F2011.0070, by Mary Miller. Study conducted at ATS Labs. Study completion date – April 18, 2012. Project Number A12454.

The active ingredient concentration of Batch 11gnr03 was reported to be 0.340% sodium hypochlorite and Batch 11gnr05 was reported to be 0.343% sodium hypochlorite.

This study was conducted against Avian Influenza A (H5N1) strain VNH5N1-PR8/CDC-RG (CDC# 2006719965) using RMK cells (Rhesus Monkey Kidney cells; obtained from Viromed Laboratories, Inc.) as the host system. Two lots (Batch 11gnr03/04 and 11gnr05/06) of GNR were tested according to ATS Labs Protocol No. CX18103111.AFLU (copy provided). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 22.0°C at 18.5% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed with 3 sprays at a distance of 6-8 inches and held covered for 30 seconds at 22.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V. RESULTS

MRID Number	Organism	No. Carriers Exhibiting Growth/ Total No. Tested				Carrier Population (Log_{10})
		Batch 11gnr03/04	Batch 11gnr05/06	Batch 11gnr01/02 (≥60 days old)	Batch 11gnr01/ 11gnr17** (≥60 days old)	
488850-12	*Staphylococcus aureus* (ATCC 6538)	1/60	0/60	1/60	-	6.67
488850-13	*Staphylococcus aureus* (ATCC 6538)	-	-	-	0/60	6.86
488850-14	*Salmonella enterica* (ATCC 10708)	0/60	0/60	0/60	-	4.46
488850-15	*Salmonella enterica* (ATCC 10708)	-	-	-	0/60	4.42
488850-16	*Pseudomonas aeruginosa* (ATCC 15442)	0/60	0/60	1/60	-	6.22
488850-17	*Pseudomonas aeruginosa* (ATCC 15442)	-	-	-	1/60	6.39
488850-18	*Escherichia coli* O157:H7 (ATCC 35150)	0/10	0/10	-	-	5.86
488850-19	*Enterobacter aerogenes* (ATCC 13048)	0/10	0/10	-	-	7.16
488850-20	*Enterobacter cloacae* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC1000654)	0/10	0/10	-	-	6.08
488850-21	*Klebsiella pneumonia* New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000527)	0/10	0/10	-	-	6.53
488850-22	*Proteus mirabilis* (ATTC 9240)	0/10	0/10	-	-	6.88
488850-23	*Serratia marcescens* (ATCC 14756)	0/10	0/10	-	-	6.74
488850-24	*Acinetobacter baumannii* (ATCC 19606)	0/10	0/10	-	-	5.49
488850-25	Vancomycin Resistant *Enterococcus faecalis* (VRE) (ATCC 51575)	0/10	0/10	-	-	5.45
488850-26	Multidrug Resistant *Enterococcus faecium* (ATCC 12442)	0/10	0/10	-	-	5.98
488850-27	Methicillin Resistant *Staphylococcus* aureus (MRSA) (ATCC 33592)	0/10	0/10	-	-	6.48
488850-	Multidrug Resistant	0/10	0/10	-	-	4.85

28	*Streptococcus pneumoniae* (ATCC 700677)					
488850-29	*Stenotrophomonas maltophilia* (ATCC 25596)	0/10	0/10	-	-	7.01
488850-30	*Campylobacter jejuni* (ATCC 29428)	0/10	0/10	-	-	4.23
488850-32	*Candida albicans* (ATCC 10231)	0/10	0/10	-	-	5.77
488850-33	*Trichophyton mentagrophytes* (ATTC 9533)	0/10	0/10	-	-	5.66

**See discussion volume, MRID 488850-11, for explanation of fourth tested lot.

Hard Surface Virucidal Disinfection Results:

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
		Description	**Batch11gnr03 / 11gnr04** (≥60 days old)	**Batch 11gnr05/ 11gnr06** (≥60 days old)	
488850-34	Hepatitis B Virus (Duck Hepatitis B as surrogate)	10^{-1} to 10^{-4} dilutions	Complete Inactivation	Complete Inactivation	($TCID_{50}$/0.25 mL) $10^{5.75}$
		$TCID_{50}$/0.25mL	$\leq 10^{0.50}$, $\leq 10^{0.50}$	$\leq 10^{0.50}$, $\leq 10^{0.50}$	
		TCD_{50}/0.25mL	$\leq 10^{0.50}$, $\leq 10^{0.50}$	$\leq 10^{0.50}$, $\leq 10^{0.50}$	
		Log Reduction	$\geq$5.56, $\geq$5.56	$\geq$5.56, $\geq$5.56	
488850-35	Hepatitis B Virus (Duck Hepatitis B as surrogate) Confirmatory	10^{-1} to 10^{-4} dilutions	Complete Inactivation	-	($TCID_{50}$/0.25 mL) $10^{5.75}$
		$TCID_{50}$/0.25mL	$\leq 10^{0.50}$, $\leq 10^{0.50}$	-	
		TCD_{50}/0.25mL	$\leq 10^{0.50}$, $\leq 10^{0.50}$	-	
		Log Reduction	$\geq$5.56, $\geq$5.56	-	
488850-36	Herpes Simplex Virus type 1	10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	$\geq$5.00	$\geq$5.00	
488850-37	Human Immuno-deficiency Virus type 1 (HIV)	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{5.50}$
		10^{-3} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.2mL	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		TCD_{50}/0.2mL	$10^{2.50}$	$10^{2.50}$	
		Log Reduction	$\geq$3.00	$\geq$3.00	
488850-38	Influenza A	10^{-1} to 10^{-8} dilutions	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{6.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	

		Log Reduction	≥6.00	≥6.00	
488850-39	Rhinovirus type 37	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.00	≥4.00	
488850-40	Rotavirus Strain WA	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.25	≥4.25	
488850-41	Norovirus (Feline Calicivirus Surrogate)	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{6.75-7.00}$
		10^{-2} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{1.50}$, $\leq 10^{1.50}$	$\leq 10^{1.50}$, $\leq 10^{1.50}$	
		TCD_{50}/0.1mL	$10^{1.50}$, $10^{1.50}$	$10^{1.50}$, $10^{1.50}$	
		Log Reduction	≥5.34, ≥5.34	≥5.34, ≥5.34	
488850-42	Norovirus (Feline Calicivirus Surrogate) Confirmatory	10^{-1} dilution	Cytotoxicity	-	$10^{5.75-6.00}$
		10^{-2} to 10^{-4} dilutions	Complete inactivation	-	
		$TCID_{50}$/0.1mL	$\leq 10^{1.50}$, $\leq 10^{1.50}$	-	
		TCD_{50}/0.1mL	$10^{1.50}$, $10^{1.50}$	-	
		Log Reduction	≥4.30, ≥4.30	-	
488850-43	Human Coronavirus	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.75	≥4.75	
488850-44	Respiratory syncytial virus (RSV)	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.00	≥4.00	
488850-45	Avian Influenza A (H5N1)	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{5.00}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.50	≥4.50	

Hard Surface *C. difficile* Sporicidal Disinfection Results: MRID 488850-31

Test Results

Lot Code	Carrier Number	Mean CFU/carrier	Mean Log_{10} CFU/carrier	Mean Log_{10} Reduction
11gnr01/17	1-10	<1	<0.0	>6.50
11gnr03/04	1-10	<1	<0.0	>6.50
11gnr05/06	1-10	<1	<0.0	>6.50

Untreated Dried Carrier Control Results:

Untreated Carrier No.	CFU/carrier	Log_{10} Carrier	Mean Log_{10} Density
1	3.4×10^6	6.53	6.50
2	2.3×10^6	6.36	
3	4.1×10^6	6.61	

HCl Resistance Control Results:

Test Organism	Mean Log_{10} Reduction		
	5 minutes	10 minutes	20 minutes
C. difficile spores	0.67	1.11 (PASS)	1.67

VI. CONCLUSION

1. The submitted efficacy data supports the use of the product, GNR, as a disinfectant with bactericidal activity against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load for a 40 or less second contact time:

MRID 488850-12, 488850-13	*Staphylococcus aureus*
MRID 488850-14, 488850-15	*Salmonella enterica*
MRID 488850-16, 488850-17	*Pseudomonas aeruginosa*
MRID 488850-18	*Escherichia coli* O157:H7
MRID 488850-19	*Enterobacter aerogenes*
MRID 488850-20	*Enterobacter cloacae* New Delhi Metallo-Beta Lactamase-1
MRID 488850-21	*Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase-1
MRID 488850-22	*Proteus mirabilis*
MRID 488850-23	*Serratia marcescens*
MRID 488850-24	*Acinetobacter baumannii*
MRID 488850-25	Vancomycin Resistant *Enterococcus faecalis*
MRID 488850-26	Multidrug Resistant *Enterococcus faecium*
MRID 488850-27	Methicillin Resistant *Staphylococcus aureus*
MRID 488850-28	Multidrug Resistant *Streptococcus pneumoniae*
MRID 488850-29	*Stenotrophomonas maltophilia*
MRID 488850-30	*Campylobacter jejuni*

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. At least one of the product lots tested against *S. aureus, S. enterica,* and *P. aeruginosa* was at least 60 days old at the time of testing. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, GNR, as a disinfectant with fungicidal activity against the following fungi in the presence of a 5% organic soil load for a 1 minute contact time:

(MRID 488850-32)	*Candida albicans*
(MRID 488850-33)	*Trichophyton mentagrophytes*

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data support the use of the product, GNR, as a disinfectant with virucidal activity against the viral strains listed below on hard, non-porous surfaces in the presence of at least 5% organic soil load for a 30-second contact time:

MRID 488850-34, 488850-35	Hepatitis B Virus
MRID 488850-36	Herpes Simplex Virus type 1
MRID 488850-37	Human Immodeficiency Virus type 1
MRID 488850-38	Influenza A virus
MRID 488850-39	Rhinovirus type 37
MRID 488850-40	Rotavirus
MRID 488850-41, 488850-42	Norovirus (Feline Calicivirus as surrogate)
MRID 488850-43	Human Coronavirus
MRID 488850-44	Respiratory Syncytial Virus (RSV)
MRID 488850-45	Avian Influenza A (H5N1)

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was indicated in all dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

4. The submitted efficacy data **do not support** the use of the product, GNR, as a disinfectant with sporicidal activity against the spore form of *Clostridium difficile* (ATCC 43598) on hard, nonporous surfaces in the presence of no organic soil load for a 50-second contact time. **Population control Carriers were not treated in the same manner as the treated carrier for this major deviation of the QCT-II method** (Petri dishes versus vials, filter paper padding versus none, and 8 sprays versus unspecified number of sprays). This may affect the number of recoverable spores on the population control.

VI. LABEL

1. The proposed label claims are acceptable regarding the use of the product, GNR, as a disinfectant with bactericidal activity for use on hard, non-porous surfaces against the following microorganisms when used undiluted in the presence of 5% organic soil, at room temperature, for a 40 second contact time:

Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)
Pseudomonas aeruginosa (ATCC 15442)
Escherichia coli O157:H7 (ATCC 35150)
Enterobacter aerogenes (ATCC 13048)
Enterobacter cloacae New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000654)
Klebsiella pneumonia New Delhi Metallo-Beta Lactamase-1 (NDM-1) (CDC 1000527)
Proteus mirabilis (ATCC 9240)
Serratia marcescens (ATCC 14756)
Acinetobacter baumanni (ATCC 19606)
Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575)
Multidrug Resistant *Enterococcus faecium* (ATCC 51559)

Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)
Multidrug Resistant *Streptococcus pneumoniae* (ATCC 700677) (**must remove the following drugs from the listed drugs: Penicillin (nonmening), Ceftriaxone (nonmening), Azithromycin, and Ertapenem (see page 9 of the proposed label)**)
Stenotrophomonas maltophilia (ATCC 25596)
Campylobacter jejuni (ATCC 29428)

These claims **are supported** by the applicant's data.

2. The proposed label claims are acceptable regarding the use of the product, GNR, as a disinfectant with fungicidal activity on hard, non-porous surfaces against the following when used as it is in the presence of 5% organic soil, at room temperature, for a contact time of 1 minute:

Candida albicans (ATCC 10231)
Trichophyton mentagrophytes (ATTCC 9533)

This claim **is supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, GNR, as a disinfectant with virucidal activity on hard, non-porous surfaces when used as it is in the presence of at least 5% organic soil, at room temperature, for a contact time of 30 seconds for:

Hepatitis B Virus
Herpes Simplex Virus type 1, Strain F(1) (ATCC VR-733)
Human Immodeficiency Virus type 1, Strain HTLV-III_B
Influenza A virus, Strain Hong Kong (ATCC VR-544)
Rhinovirus type 37, Strain 151-1 (ATCC VR-1147)
Rotavirus, Strain WA
Feline Calicivirus, Strain F-9 (ATCC VR-782) (surrogate for Norovirus)
Coronavirus, 229E strain (ATCC VR-740)
Respiratory Syncytial Virus (RSV), Strain Long (ATCC VR 26)
Avian Influenza A (H5N1) virus, Strain VNH5N1-PR8/CDC-RG (CDC # 20006719965)

These claims **are supported** by the applicant's data.

4. The proposed label claims are **unacceptable** regarding the use of the product, GNR, as a disinfectant with sporicidal activity on hard, non-porous surfaces when used as it is in the presence of no organic soil, at room temperature, for a contact time of 50 seconds against the spore form *Clostridium difficile* (ATCC 43598). **Registrant must remove *Clostridium difficile* (ATCC 43598) and all related claims from the label**.

5. The applicant must make the following changes to the proposed label, as appropriate:

- On page 3 of the proposed label, under Deodorization, remove "Let stand for appropriate .....[organisms]." Deodorization claim cannot be associated with microorganisms killing.

- On page 3 of the proposed label, under Disinfectant, remove "Rinse with potable water for food-contact surfaces" and emphasize on "Do not use on food-contact surfaces". Potable water rinse does not take away uncleared substances for food use.

- On page 6 of the proposed label, under Stains/Soil, remove "Mold Stains". There is no mold stain without mold and product is not carrying mold claims.